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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/505,458 02/11/00 ROSEN

M 61020-A/HOW/

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QM12/0712

EXAMINER

OROPEZA, F

ART UNIT

PAPER NUMBER

3762

DATE MAILED:

07/12/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/505,458

Applicant(s)

ROSEN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on June 18, 200 have been fully considered by the are not persuasive.
2. Claims 1, 2, 9-13, 20-21, 28-32, 39-40 and 47-51 stand rejected under 35 U.S.C.102(e) as being clearly anticipated by Knisley (US 5824028) for the reasons of record.
3. Applicant states Kinsley (US 5824028) does not disclose signals:
 - in the form of periodic electrical signal, or
 - delivered through the use of electrode pairs.

Kinsley discloses alternate leads and electrode combinations to provide variation in the polarity, timing and/or waveform shape (column 3, lines 23-34); variations in timing is read to be periodic electrical signals. Periodic signal is also disclosed in the Abstract as pacing (line 12). Kinsley discloses an electrode pair (column 3, lines 23-26).

4. Applicant states Kinsley (US 5824028) does not disclose that gap junctions will be remodeled. The invention disclosed by Kinsley is understood to remodel the gap junctions as indicated by:
 - the recognition that "effects on stimulation" "result from changes in transmembrane ion channels" (column 1, lines 19-23); the junction gaps are read to be the transmembrane ion channels, and
 - the recognition that "effects on stimulation" "result from changes in transmembrane ion channels" (column 1, lines 19-23), hence the gap junctions are being remodeled.

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5. Applicant states Kinsley (US 5824028) does not disclose that effective refractory period will be altered. The invention disclosed by Kinsley is understood to alter the effective refractory period as indicated by recognition that the “transmembrane voltage” changes “the state of transmembrane voltage-dependent ion channels that produce excitation or graded response” (column 1, lines 28-32); a graded response is understood to be a refractory period. Refractory tissue is also disclosed (column 3, lines 35-49).

6. Claims 1, 10-12, 20, 29-31, 39 and 47-50 stand rejected under U.S.C. 102(b) as being clearly anticipated by Kroll et al. (US 5366485) for the reasons of record.

7. Applicant states Knoll et al. (US 5366485) does not mention or suggest remodeling gap junctions. The invention disclosed by Knoll et al. impacts the heart cell function by defibrillation. The impact on the heart cell function includes alteration of the “sodium channels”, “sodium channels” are understood as the gap junctions, hence changing or remodeling the gap junctions is disclosed (column 4, line 46 – column 5, line 45).

8. Applicant states Knoll et al. (US 5366485) expressly teaches away from using linked multiple electrode pairs. The invention disclosed by Knoll et al. teaches the uses of large surface area electrodes, understood to contain linked multiple electrode pairs (column 7, lines 43-47).

9. Applicant states Knoll et al. (US 5366485) does not teach or suggest altering the effective refractory period of the heart. The invention disclosed by Knoll et al. teaches that defibrillation impacts the refractory time and refractory period; during the refractory period, the cell is incapable of responding to another stimulus (column 5, lines 36-45).

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10. Claims 3, 7-8, 14, 17-19, 22, 26-27, 33, 36-38, 41, 45-46, 52, and 55-57 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over Knisley (US 58240280) in view of Dahl et al. (US 5203348) for the reasons of record.

11. Applicant states that there is not motivation to combine Kinsley (US 5824028), Dahl et al. (US 5203348), and Ideker (US 5873896). All three inventions are epicardial leads, Kinsley (column 2, lines 31-35), Dahl et al. (column 4, lines 20-25), and Ideker (column 1, lines 45-49), hence it is found one skilled in the art would be motivated to combine these references.

Claim Objections

12. Claims 58, 59, and 60 are objected to because of the following informalities:

- In claim 58, line 3, "of heart" should be --of a heart--,
- In claim 59, line 4, "of heart" should be --of a heart--, and
- In claim 60, line 3, "of heart" should be --of a heart--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knisley (US 5824028) in view of Ideker (US 5873893). Knisley discloses a method and device with electrode(s) oriented relative to cardiac fiber direction whereby the stimulation pulse reduces the non-uniformity of the transmembrane voltage change associated with arrhythmic conditions. The invention includes an electrical pulse generator (26), a lead assembly (25), and a plurality of electrodes (12). This invention focuses on the transmembrane potential and ion channels (column 1, lines 11-54) and recognizes the impact of treatment on the refractory tissue (column 3, lines 35-49).

- This invention is understood to impact junction gap remodeling as indicated by the recognition that "effects on stimulation" "result from changes in transmembrane ion channels" (column 1, lines 19-23); the junction gaps are read to be the transmembrane ion channels.
- The invention is understood to alter the effective refractory period as indicated by the recognition that "transmembrane voltage" changes "the state of transmembrane voltage-dependent ion channels that produce excitation or graded response" (column 1, line 28-32); a graded response is understood to be a refractory period.
- This invention is understood to induct ion channel remodeling as indicated by the recognition that "effects on stimulation" "result from changes in transmembrane ion channels" (column 1, lines 19-23), hence the ion channels are being remodeled.

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The electrode can be inserted in the myocardium, positioned to contract the epicardium or endocardium, or be a flat ribbon (column 2, lines 31-46). Sutures (column 2, line 66 – column 3, line 2) can attach the electrode. Alternate leads and electrode combinations are discussed to provide variation in the polarity, timing and/or waveform shape (column 3, lines 23-34); variations in timing is read to be periodic electrical signals. As discussed above, Knisley discloses the claimed invention except for disclosing the electrode pairs are arranged in two columns, with one electrode in each pair in one column, and the other electrode in each pair in the other column.

Ideker discloses a cardiac device for reducing arrhythmia and teaches that it is known to use an electrode configuration of an elongated primary strip having a plurality of electrodes positioned at spaced intervals, e.g. 1-4 millimeters (column 3, lines 2-4), along its length. Figure 5, shows electrodes mounted on a substrate. A column of electrodes are read to be the line of electrodes perpendicular to the long edge of strips 12 and 50, and the pairs are read to be the electrodes side-by side on strips 12 and 50.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode as taught by Knisley device, with the elongated primary strip as taught by Ideker. One have ordinary skill in the art would have been motivated to make such a modification in electrode to gain a low energy level stimulation that causes the patient minimal discomfort (column 1, lines 63-67).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO

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GEORGE R. EVANISKO
PRIMARY EXAMINER

7/11/11